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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,291	08/17/2001	Gary L. Cantrell	MRD/53	4770
26875	7590	05/04/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/932,291	CANTRELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 1/11/02; 3/12/02; and 2/13/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/11/02 &amp; 3/12/02</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### APPLICANT'S INVENTION

1. The instant invention is directed to compositions and methods thereof wherein an organized mobile multicomponent conjugate assembly is utilized.

**Note:** Claims 1-47 are pending.

### RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group IV (claims 29-47) and the species wherein A1 and A2 = CH<sub>3</sub>(CH<sub>2</sub>)<sub>a</sub>-W; a = 16-32; W = oxygen; B1 = glucose; B2 = sialic acid; lamellar structure = CH<sub>3</sub>-(CH<sub>2</sub>)<sub>e</sub>-X; e = 16-32; X = sulfate; effector molecule = optical agent; and L1 and L2 = polyethylene glycol, filed 2/13/04, and the election of the species of compound 37 (Figure 19), filed 2/25/04, is acknowledged. It is duly noted that in the response, Applicant stated that the election was made with traverse.

However, no arguments were presented stating that the restriction and election were improper. Hence, the restriction is viewed as proper and is thus maintained. Therefore, the restriction and election of species requirements are deemed proper and is made FINAL.

**Note:** Initially, the Examiner searched for Applicant's elected species.

Therefore, since no prior art was found to reject Applicant's elected species, the search was expanded to lamellar structures in general. However, it should be noted that no art may have been found because the claims are not clear and concise.

### WITHDRAWN CLAIMS

3. Claims 1-28 are withdrawn from consideration as not being directed to the elected invention.

## 112 FIRST PARAGRAPH REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising lamellar structures disclosed in Table 3; linkers disclosed in Table 4; anchors disclosed in Table 1; and binding epitopes disclosed in Table 2, does not reasonably provide enablement for all organized mobile multicomponent conjugate assemblies as set forth in independent claim 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7)

Art Unit: 1616

breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of using a multicomponent conjugate system.

(2) State of the prior art

The references of record do not indicate which specific multicomponent conjugate system combinations are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 29 encompasses a vast number of possible multicomponent conjugate system combinations comprising a lamellar structure, binding compounds, linkers, and an effector molecule. Applicant's specification does not enable the public to make or use such a vast number of possible multicomponent conjugate systems.

(4) Level of predictability in the art

The art pertaining to the multicomponent conjugate systems is highly unpredictable since in the art reference is generally made to a lamellar structure without assigning a specific formula to such structure (see the cited prior art below). Determining the multicomponent conjugate systems useful with the instant invention requires various experimental procedures and without guidance that is applicable to all multicomponent lamellar containing conjugate systems, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 29 encompasses a vast number of multicomponent systems comprising a lamellar structure, binding compounds, anchor regions, linkers, and effector regions. Applicant's limited guidance does not enable the public to prepare such numerous amounts of multicomponent system combinations. There is no directional guidance for multicomponent systems except the lamellar structures disclosed in Table 3; the linkers disclosed in Table 4; the anchors disclosed in Table 1; and the binding epitopes disclosed in Table 2. Therefore, there is no enablement for all organized mobile multicomponent conjugate assemblies.

(6) Existence of working examples

Independent claim 29 encompasses a vast number of multicomponent systems. Applicant's limited working examples do not enable the public to prepare such numerous amounts of multicomponent systems. While Applicant's claims encompass a plethora of possible multicomponent systems, the specification provides for multicomponent systems having the lamellar structures disclosed in Table 3; linkers disclosed in Table 4; anchors disclosed in Table 1; and binding epitopes disclosed in Table 2.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible multicomponent systems known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

Art Unit: 1616

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

## **112 SECOND PARAGRAPH REJECTIONS**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-47: The claims as written are ambiguous because one cannot readily ascertain what multicomponent systems are encompassed by the instant invention. Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

Claims 29-47: The claims as written are ambiguous because it is unclear what diagnostic/therapeutic method Applicant is referring to. Is Applicant referring to imaging, chemotherapy, phototherapy, and radiotherapy? Please clarify so that one may readily determine what is being claimed.

Art Unit: 1616

Claims 30-32, and 34-36: The claims as written are ambiguous because it is unclear what Applicant intend the variables to be. Specifically, the use of 'may be' indicates that there are other possible definitions that the variables may be assigned. Thus, Applicant is respectfully requested to replace 'may be' with 'is' to clarify the claims.

Claims 29-47: The claims are confusing because Applicant has not identified all of the variables in the independent claim. Specifically, the variables A1, A2, B1, B2, L1, and L2 have not been defined in independent claim 29.

Claims 29-47: The claims are ambiguous because they do not clearly set forth what Applicant intends to be the method steps. Thus, it is respectfully suggested that Applicant insert 'said method' in line 2 before 'comprising' to clarify that Applicant is identifying the method steps, not composition components.

## 103 REJECTIONS

8. The following is a quotation of 35 USC 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in sections 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 29, 31, 32, 35, 36, 38-42, and 45-47 are rejected under 35 USC 103(a) as being unpatentable over Garrity et al (US Patent No. 6,045,821).

**Garrity et al** disclose a liposomal agent comprising liposomes having bound to a membrane thereof a chelated metal useful for diagnostic or therapeutic purposes (see



Art Unit: 1616

entire document, especially, abstract). In addition, Garrity et al disclose (1) the liposomes may be used to target specific organs such as the liver, spleen, lung, lymphatic system, vasculature, or bone marrow (column 2, lines 3-12). (2) The metals which may be present depend upon the desired end use of the liposomal agents (column 8, lines 45-49). (3) The liposomes have multiple lamellars (multilamellar) [column 8, lines 56-61; columns 8-9, bridging paragraph]. (4) Modifiers such as polyethylene glycol may be incorporated into the lamellar structures to extend the blood half life (column 9, lines 59-68). (5) The liposomes may be generated from perfluorinated phospholipids (column 10, lines 1-4). (6) Active targeting to specific organs/tissues may be achieved by incorporating lipids with attached antibodies that are specific for tumor associated antigen, lectins, or peptides (column 10, lines 5-8; column 14, lines 33-40). (7) Contrast agents may be generated wherein the liposomes are formulated in physiologically tolerable medium wherein one or more additive such as pH modifying agents, chelating agents (i.e., EDTA and DTPA), antioxidants, tonicity modifying agents (i.e., glucose), or cryoprotectants (i.e., glucose and polyethylene glycol) [column 11, lines 59-65; column 12, lines 11-32]. (8) Possible metals include Gd, Ho, Sm, Mn, Re, and Tc (column 13, lines 2-17). (9) The imaging agents may have an absorbance/emission in the range of 670-1300 nanometers (column 13, lines 24-28). (10) Possible linkers include carboxylic or carbonic esters, disulfides, acetal, ketal, thioesters, carbamates, amides, and so forth (columns 13-14, bridging paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a multicomponent lamellar containing structure for

Art Unit: 1616

diagnostic and therapeutic purposes because Garrity et al discloses that their invention encompasses a multilamellar structure which may be used for diagnostic or therapeutic purposes. In addition, the reference discloses that components such as polyethylene glycol, linkers, metals (i.e., Gd, Ho, Mn, Sm, Re, Tc), perfluorinated phospholipids, targeting agents, chelating agents, tonicity agents (i.e., glucose), and cryoprotectants (i.e., glucose and polyethylene glycol). Hence, both Applicant and Garrity et al disclose multicomponent systems comprising lamellar structures.

**COMMENTS/NOTES**

10. Applicant is reminded that the recitation 'capable of' is not a positive claim limitation because it only requires the ability to so perform that function. Hence, for example, the phrase 'capable of binding' may be replaced with 'binds' to clearly indicate that binding occurs as opposed to the possibility that binding may occur.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

April 28, 2004